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Via Federal Express

Document Processing Center (7407M) EPA East – Room 6428 (Attn: TSCA Section 8(e) Coordinator)

CONTAINS TSCA CONFIDENTIAL RUSINESS INFORMATION

Light is the section of Coordinator)	DUSINESS INFORMATION
U.S. Environmental Protection Agency	
1201 Constitution Avenue, NW Washington, DC 20004-3302	
washington, DC 20004-3302	
Re: (CASRN)	SCA Section 8(e) Submission for
Dear Sir or Madam:	
Protection Agency ("EPA") under section 8(einformation regarding a draft report on a four substance, which has the Chemical Agency ("EPA") under section 8(einformation regarding a draft report on a four substance.	hereby submits to the U.S. Environmental e) of the Toxic Substances Control Act ("TSCA") -week oral toxicity study in rats using the test Abstracts Service Registry Number ("CASRN") Inventory. The test substance was imported for exemption.
four consecutive weeks. Four groups, each of item by gavage at dosages of 5, 20 and 60 mg group, 200 mg/kg/day from Day 1 to Day 19 females). The control and high dose groups of	studied the oral toxicity of of four consecutive weeks. Draft data also tential treatment-related effects over a period of five male and five female rats, received the test t/kg/day (for males) and 20, 60 and, in the high dose and 100 mg/kg/day from Day 20 to Day 28 (for consisted of additional 5 males + 5 females for the during dosing and at necropsy. See Attachment 1
If you have any questions regarding that at or	nis submission, please do not hesitate to contact.
\$	Sincerely,
	, President
Enclosure – Attachment 1	

Attachment 1

Summary of Draft Report Results

toxicity of when administered daily to rats over a period of four consecutive weeks followed by a recovery period of four weeks from the last administration. Toxicity features were investigated in four main groups (Groups 1-4), each group comprised of five male and five female rats. The control and high dose groups consisted of additional 5 males + 5 females for the recovery period. Males were dosed at 5, 20 and 60 mg/kg/day. Females were dosed at 20, 60 and, in the high-dose group, 200 mg/kg/day from Day 1 to Day 19 and 100 mg/kg/day from Day 20 to Day 28.

Data present signs of dose-related adverse toxic effects, some of which were not reversible up to four weeks following termination of exposure. Mortality occurred in three female animals of Group 4 when treated at 200 mg/kg/day (the high-dose group). Based on macroscopic and microscopic observations, the cause of death in these animals was considered to be related to the test compound. Reductions of body weight were observed in the treated groups, and a partial recovery was evident in both sexes at the end of recovery.

The liver was identified as the main target organ. Liver damage consisted of treatment-related dose-dependent degenerative microscopic findings, associated with high increase of organ size and weight, and threshold-like increase of liver enzymatic activity (e.g., Cytochrome p450 and cyanide-insensitive palmitoyl CoA oxidase). The morphological aspect of the hepatocytic hypertrophy was consistent with proliferation of smooth endoplasmic reticulum. At the low doses (5 mg/kg/day in males and 20 mg/kg/day in females), diffused moderate hepatocytic hypertrophy, which consisted of increased cytoplasmic eosinophilia and is occasionally associated with minimal to mild hepatocytic degeneration, was still noted.

Secondary findings in a number of organs were recorded in males treated at 60 mg/kg/day and in females treated at 200/100 mg/kg/day, which reflect a non-specific high-dose stress effect associated with a significantly reduced body weight loss.

Partial recovery of liver findings was found in the high-dose animals after a four-week recovery period (including the assayed enzymatic activities and macroscopic and microscopic findings). However, some secondary findings in blood parameters and in organ weights were still observed in both sexes at the end of the study. This demonstrates that a four-week recovery period is not sufficient for complete recovery from the findings observed after treatment in the experimental conditions used.

Based on the draft study results, a no observed adverse effect level ("NOAEL") could not be established for the substance.